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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003901971 for a patent by DUGAL SIMON STEWART JAMES as filed on 23 April 2003.

WITNESS my hand this
Fifth day of May 2004

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AUSTRALIA
Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: A FIXATION DEVICE AND METHOD OF FIXATION

Applicant: DUGAL SIMON STEWART JAMES

The invention is described in the following statement:

A FIXATION DEVICE AND METHOD OF FIXATION

Field of the invention

This invention relates to a method of fixing a first member in a position relative to a second member and a fixation device for doing the same. It relates particularly but not exclusively to a fixation device and method for its use and a tool for using the fixation device.

Background to the invention

Bones, including joints of the body are susceptible to injury including dislocation, fracture and damage as a result of trauma, disease and degenerative change. There are many ways of reducing a fracture, employing open or closed reduction such as casting, external fixation, wiring and plating. Casting and other forms of closed reduction involves aligning the broken or dislocated bone manually and setting it, usually by applying a cast. This is beneficial because it avoids the trauma of surgery and is relatively inexpensive. However, it is only suitable for relatively simple fractures and requires immobilisation of the bone which can cause stiffness and impede rehabilitation.

External fixation involves the insertion of pins into bone fragments and connecting the pins using a bar or frame which sits outside the fracture site. Although this facilitates reduction of more complex fractures, it can cause irritation of the skin and soft tissue around the pins causing infection or scarring which may compromise outcomes. Open reduction and internal fixation requires extensive exposure to allow for the approximation of bone fragments and the introduction of fixation devices.

In each case, the procedure must be performed with a high degree of accuracy to ensure that the bone is not damaged further and that it is correctly realigned with respect to its anatomic and biomechanical axes.

Summary of the invention

According to a first aspect of the present invention, there is provided a method of fixing a first member in a position relative to a second member. The method includes forming a threaded bore in the first and second members and introducing a fixation device into the threaded bore. The fixation device has a

shaft with a longitudinal axis and a first screw portion rotatable about the shaft's axis. A second screw portion is rotatable about the shaft's axis independently of the first screw portion. The first and second screw portions each have an external screw thread for engaging the threaded bore in the first and second members respectively. The fixation device is operated in such a way that one of the first or second screw portions rotates relative to the threaded bore thereby positioning the first member relative to the second member. The fixation device is then locked preferably using a grub screw which intum locks the position of the first member relative to the second member.

Preferably, the threaded bore is formed by drilling a guide wire through the first member and into the second member and using a cannulated over-drill to establish the bore. The bore may then be tapped with a screw thread. Preferably, the fixation device has a canal facilitating passage of the fixation device over the guide wire in such a way that the fixation device is introduced into the bore over the guide wire.

Preferably, the method further includes the step of introducing the fixation device by rotation of both the first and second screw portions together to move the fixation device within the threaded bore, either advancing the device into the bore or retracting it.

Preferably, the method further includes the step of introducing one or more further parallel guide wires into the threaded bore to control a torque reaction that may develop in the first and/or second members, distorting their axial relationship.

Preferably, the threaded bore is a blind bore which ends in the second member. In such an embodiment, the fixation device may be advanced into the blind threaded bore until it reaches the end of the bore to minimise weakness in the members resulting from the presence of the threaded bore.

In a preferred embodiment, the first screw portion is a collar screw fitted over and freely rotatable about the shaft's axis and the second screw portion is a collar screw threaded onto the shaft between the first and second screw portions

Preferably, the first or second or both the first and second members are bone. Alternatively, the first and/or second members are another suitable material such as wood, plastic or a suitable metal or polymer material.

In a second aspect of the invention there is provided a fixation device for fixing a first member in a position relative to a second member. The fixation device includes a shaft having a longitudinal axis, a first screw portion rotatable about the shaft's axis and a second screw portion rotatable about the shaft's axis independently of the first screw portion. The first and second screw portions each have an external screw thread for engaging a threaded bore in the first and second members respectively.

Preferably, the shaft further includes a head, and the first screw portion is a collar screw fitted over the shaft between the head and the second screw portion so that the head retains the first screw portion in the fixation device.

Preferably, the second screw portion is a collar screw threaded onto the shaft and held in position by a lock nut which is threaded onto the shaft between the first and second screw portions.

The fixation device may be formed of any material which is suitable for joining the first and second members. In a preferred embodiment where at least one of the first and second members is bone, the fixation device is formed of a metallic, ceramic, polymer or other material which cause little or no reaction with the body system in which the bone exists. The shaft may be rigid or flexible.

Preferably, the fixation device includes a first engaging region on the first screw portion for engaging a tool which rotates the first screw portion relative to the first member. The fixation device may also include a second engaging region for engaging a tool which rotates the second screw portion relative to the second member. The fixation device may also include retaining means for retaining the fixation device within the threaded bore. Such retaining means may be in the form of a threaded lock (grub) screw or other suitable device preventing relative motion between the first and second screw portions and the shaft.

Preferably, the fixation device has a canal facilitating passage of the fixation device over a guide wire.

In a third aspect of the present invention, there is provided a tool for positioning a fixation device inside a threaded bore in a first and second member. The tool includes a first engaging portion for engaging part of the fixation device which rotates relative to the first member. A second engaging portion engages part of the fixation device which rotates relative to the second

member and is operable independently of the first engaging portion. A locking mechanism is provided to lock movement of the first engaging portion relative to the second engaging portion.

Preferably, the tool includes a shaft with independently operable inner and outer shaft portions. In such an embodiment, the outer shaft portion is the first engaging portion and the inner shaft portion is the second engaging portion. Preferably, at least the first and second engaging portions are cannulated.

Brief description of the drawings

The invention will now be described in greater detail with reference to the embodiments illustrated in the accompanying drawings. It is to be understood that the particularity of the accompanying drawings does not supersede the generality of the preceding description of the invention.

Figure 1a shows a sectional view of a fixation device being inserted into a threaded bore in accordance with an embodiment of the invention.

Figure 1b shows the sectional view of Figure 1a after operation of the fixation device to position the first member relative to the second member.

Figure 2a shows a sectional view of a fixation device being inserted into a threaded bore in accordance with another embodiment of the invention where the depth of the second member is small.

Figure 2b shows the sectional view of Figure 2a after operation of the fixation device to position the first member relative to the second member.

Figure 2c shows a sectional view of a further embodiment of the invention after operation of the fixation device for the purpose of holding the two members separated by a predetermined interval.

Figure 3 shows a sectional view of a fixation device according to an embodiment of the invention.

Figure 4a shows a sectional view of a tool for positioning a fixation device in accordance with an embodiment of the invention.

Figure 4b shows the sectional view of Figure 4a with the locking mechanism activated.

Figure 5a illustrates rigid shaft suitable for use according to an embodiment of the invention.

Figure 5b illustrates a flexible shaft suitable for use according to another embodiment of the invention.

Detailed Description

Referring firstly to Figures 1a and 1b, a preferred embodiment of the invention is illustrated. A guide wire (not shown) is drilled through first member 1, henceforth referred to first bone section 1, across fracture site 2 and into second member 3, henceforth referred to as second bone section 3. A first bore 4a is formed using a cannulated drill (not shown) to drill through first bone section 1, across fracture site 2 and into second bone section 3.

It is preferred that first bore 4a stops short of penetrating the far end of second bone section 3. A second larger diameter cannulated bit is used to drill through first bore 4a stopping just short of fracture site 2 thus forming a second bore 4b having a larger diameter. First bore 4a is tapped with a screw thread suitable for engaging first screw portion 5 and second bore 4b is tapped with a screw thread suitable for engaging second screw portion 6. For simplicity, combined threaded bores 4a and 4b will hereinafter be referred to as threaded bore 4. Fixation device 10 is then introduced into threaded bore 4.

Preferably, the overall length of threaded bore 4 is determined so that a fixation device 10 with a suitable length can be selected. Selection of a suitable fixation device may also require consideration of the diameter of the bore in the first and/or second bone sections 1,3.

Fixation device 10 (best illustrated in Figure 3) has a shaft 11, first and second screw portions 5,6 and lock nut 13. The fixation device is assembled by first passing shaft 11 through first screw portion 5 which is in the form of a larger diameter collar screw with external thread. Shaft 11 is provided with a left-hand screw thread onto which lock nut 13 is threaded. Second screw portion 6 in the form of a smaller diameter collar screw with an internal left-hand screw thread is also threaded onto shaft 11. This may be assisted by use of a device engaging head 12 of fixation device 10, such as a hex-head key. The hex-head key may be provided in the form of tool 20 illustrated in Figure 4.

Shaft 11 has a longitudinal axis about which first screw portion 5 is rotatable. Second screw portion 6 is also rotatable about the axis of shaft 11. Since second screw portion 6 is threaded onto shaft 11, rotation of screw

portion 6 will also rotate shaft 11 and vice versa. However, because first screw portion 5 is not threaded onto shaft 11 and rotates freely about it, it follows that first screw portion 5 rotates about the axis of shaft 11 independently of second screw portion 6.

As can be seen in Figure 3, first and second screw portions 5,6 each have an external screw thread which is adapted to engage threaded bore 4 in first and second bone sections 1,3 respectively. It is to be understood that the pitch of the external screw thread on first screw portion 5 is equal to the pitch of the external screw thread on second screw portion 6. Therefore, both screw portions undergo the same amount of linear translation for each degree of rotation undergone.

Fixation device 10 is introduced into threaded bore 4 over the guide wire (not shown) which aids in maintaining alignment of the bore 4 in first and second bone sections 1,3. Introduction of fixation device 10 may be aided by use of a specially designed tool such as that which is illustrated in Figure 4.

Referring now to Figure 4, tool 20 has a first engaging portion 21, a second engaging portion 22 and a locking mechanism 23 as well as a handle 24. First engaging portion 21 is provided in the form of an outer shaft for engaging part of first screw portion 5. Second engaging portion 22 is provided in the form of an inner shaft for engaging part of second screw portion 6 and is operable independently of first engaging portion 21. Locking mechanism 23 can be used to lock movement of first engaging portion 21 relative to second engaging portion 22. For simplicity, first engaging portion 21 will henceforth be referred to as outer shaft 21 and second engaging portion 22 will hence forth be referred to as inner shaft 22.

Preferably, tool 20 is cannulated with a two stage hex-head design. That is, outer and inner shafts 21,22 have a hexagonal cross-section so that inner shaft 22 engages a corresponding hex-head recess in head 12 and outer shaft 21 engages with a hex-head inner aperture provided in first screw portion 5. It is to be understood that other suitable "head" designs may be employed. Security screw heads are some existing designs which may be suitable.

With locking mechanism 23 activated, movement of inner shaft 22 relative to outer shaft 21 is fixed. Therefore, rotation of handle 24 will facilitate rotation of outer and inner shafts 21,22 together. Accordingly, first and second

screw portions 5,6 will also rotate together. This enables assembled fixation device 10 to advance into threaded bore 4 with second screw portion advancing through first bone section 1, across fracture site 2 and into a portion of threaded bore 4 formed in second bone section 3. In one embodiment, fixation device 10 is advanced until it reaches the end of tapped bore 4. Since the pitch of the external threads on first and second screw portions 5,6 are equal there is no relative movement of first bone section 1 relative to second bone section 3 by introduction of fixation device 10 into threaded bore 4. The pitch of screw thread on first and second screw portions 5,6 may be selected based on several factors such as the length of the bore and the softness of the bone being positioned. For example, a more coarse thread may be desirable when the screw portion is being screwed into softer bone.

Once fixation device 10 has been introduced into threaded bore 4, that is, it is located *in situ*, locking mechanism 23 on tool 20 is released so that outer shaft 21 rotates independently of inner shaft 22. Holding outer shaft 21 still, inner shaft 22 is rotated clockwise. Second screw portion 6 advances into second bone section 3 having the effect of drawing it toward first bone section 1 thereby closing fracture site 2. This is illustrated in Figure 1b. When the desired relative positioning of the bone sections has been achieved, tool 20 is removed and fixation device 10 is locked into position.

Preferably fixation device 10 (best shown in figures 4a and 4b) is locked into position using a cannulated lock screw 14 (best shown in Figure 3) which is introduced over the guide wire and screwed inside an internal diameter of first screw portion 5. This may be achieved using a hex-head tool. Preferably, cannulated lock screw 14 is provided with a hex-head indentation with the same dimension as the hex-head indentation in head 12. Therefore, inner shaft 22 of tool 20 is also suitable to fasten lock screw 14 and lock fixation device 10 into position. Once lock screw 14 has been advanced into first screw portion 5 so that it no longer projects beyond first screw portion 5, outer shaft 21 of tool 20 may be used to engage and hold first screw portion 5 still whilst lock screw 14 is advanced further (if necessary) into the first screw portion. Advancement of lock screw 14 should cease when it is sufficiently tightened against head 12. Once lock screw 14 is suitably positioned, the guide wires are removed and the procedure is concluded.

A variation of the above-described method is provided and may be suitable where the depth of second bone section 3 is small and movement of second screw portion 6 within the second bone section 3 should be minimised. Such an embodiment is illustrated in Figures 2a and 2b. Bore 4b is drilled and tapped stopping just short of the far cortex of second bone section 3. Fixation device 10 is selected with a length which is less than the total overall length of threaded bore 4. Fixation device 10 is introduced into threaded bore 4 over the guide wire so that second screw portion 5 is only just over fracture site 2. Using tool 2 with inner shaft 22 held still, outer shaft 21 is rotated counter clockwise causing first screw portion 5 to retract in the portion of threaded bore 4 located in first bone section 1. This has the effect of drawing first bone section 1 toward second bone section 3, to close fracture site 2. When first screw portion 5 appears about to emerge from bore 4, locking mechanism 23 is activated and outer and inner shafts 21,22 are rotated together advancing fixation device 10 further into threaded bore 4. Locking mechanism 23 can then be released and the tool used again to rotate outer shaft 21 in an anti-clockwise direction, retracting first screw portion 5. This procedure with outer and inner shafts 21,22 coupled and uncoupled is repeated until first and second bone sections 1,3 are positioned as required.

In another embodiment, peripheral guide wires are introduced in series with the central guide wire prior to drilling and tapping the bore in the first and second members and inserting the fixation device. This assists in controlling potential torque reactions that may develop between the first and second members and other bone fragments particularly when the invention is used in a surgical environment.

It is to be understood that use of the inventive method and apparatus should not be limited to closing of fracture sites. Figure 2c shows a further embodiment where first and second bone sections 1,3 have been positioned using fixation device 10 without completely closing fracture site 2.

It is to be understood that the methods exemplified herein describe only some of the ways in which the invention may be performed. As an alternative, the first and second threaded bore portions 4a and 4b may have the same diameter, eliminating the need to use 2 cannulated drill bits to form the threaded bore 4. Accordingly, first and second screw portions 5,6 can also share the

same diameter. As a further alternative, second screw portion may be welded, glued or otherwise attached to shaft 10. However, it is to be understood that using a screw thread to fasten second screw portion 6 to shaft 10 facilitates adjustment of the overall length of fixation device 10 and a favourable means for the provision of modularity with the presentation of the device components.

Although it may be preferred that shaft 10 is rigid as illustrated in Figure 5a, it may also be flexible as illustrated in Figure 5b.

Advantageously, independent rotation of first and second screw portions 5,6 facilitates multi-stage positioning of first and second bone sections 1,3 and therefore multi-stage closure or positioning of bone sections1,3 around fracture site 2. The position of first bone section 1 relative to second bone section 3 can be changed by rotating the first and/or second screw portions 5,6 without advancing entire fixation device 10 further into bore 4 or changing the overall length of the fixation device. A further advantage provided by the present invention is that fixation device 10 remains entirely within the confine of threaded bore 4. Therefore, it is ideal for application in intraarticular fixation. Moreover, when fixation device 10 is cannulated and used in conjunction with a guide wire, the invention is highly suited to the closed management of fractures by percutaneous techniques.

A primary application for the present invention is in the field of orthopaedic surgery, as a means of fixation between two bones, one fractured bone or a bone and plate or other such device. There are many different areas in the body and different areas of surgery in which the inventive method and apparatus may be useful. However, it is to be understood that the principles of the invention are also suitable for use in fields outside surgery and medicine in general. Such fields may include but are not limited to carpentry, joinery and metal fabrication.

It is to be understood that various modifications, additions and/or alterations may be made to the parts previously described without departing from the ambit of the present invention as defined in the claims appended hereto.

Claims

1. A method of fixing a first member in a position relative to a second member, the method including the steps of:

(a) forming a threaded bore in the first and second members;

(b) introducing a fixation device into the threaded bore, the fixation device having:

(i) a shaft having a longitudinal axis;

(ii) a first screw portion rotatable about the shaft's axis; and

(iii) a second screw portion rotatable about the shaft's axis independently of the first screw portion;

the first and second screw portions each having an external screw thread adapted to engage the threaded bore in the first and second members respectively;

(c) operating the fixation device in such a way that one of the first or second screw portions rotates relative to the threaded bore thereby positioning the first member relative to the second member; and

(d) locking the fixation device in position.

2. A method according to claim 1 wherein the bore is formed by performing the steps of:

(a) drilling a guide wire through the first member and into the second member;

(b) drilling the bore using a cannulated drill; and

(c) tapping the bore with a screw thread.

3. A method according to claim 2 wherein the fixation device has a canal facilitating passage of the fixation device over the guide wire, and wherein the fixation device is introduced into the threaded bore over the guide wire.

4. A method according to any one of claims 1 to 3 wherein the step of introducing the fixation device includes rotating the first and second screw portions together to move the fixation device within the threaded bore.

5. A method according to any one of claims 1 to 4 further including the step of introducing one or more further guide wires into the threaded bore to control a torque reaction in the first and/or second members.

6. A method according to any one of claims 1 to 5 wherein the threaded bore is a blind bore ending in the second member.

7. A method according to claim 6 wherein the fixation device is advanced into the blind threaded bore until it reaches the end of the bore.

8. A method according to any one of claims 1 to 7 wherein:

(a) the first screw portion is a collar screw fitted over and freely rotatable about the shaft's axis; and

(b) the second screw portion is a collar screw threaded onto the shaft and held in position by a lock nut threaded onto the shaft between the first and second screw portions.

9. A method according to any one of claims 1 to 8 wherein the first and/or second members are bone.

10. A fixation device for fixing a first member in a position relative to a second member, the fixation device including:

(a) a shaft having a longitudinal axis;

(b) a first screw portion rotatable about the shaft's axis; and

(c) a second screw portion rotatable about the shaft's axis independently of the first screw portion;

the first and second screw portions having an external screw thread adapted to engage with a threaded bore in the first and second members respectively.

11. A fixation device according to claim 10 wherein the shaft further includes a head and wherein the first screw portion is a collar screw fitted over the shaft between the head and the second screw portion, the head retaining the first screw portion in the fixation device.

12. A fixation device according to claim 10 or claim 11 wherein the second screw portion is a collar screw threaded onto the shaft and held in position by a lock nut threaded onto the shaft between the first and second screw portions.

13. A fixation device according to any one of claims 10 to 12 wherein the shaft is a flexible shaft.

14. A fixation device according to any one of claims 10 to 13 including a first engaging region on the first screw portion for engaging a tool which rotates the first screw portion relative to the first member.

15. A fixation device according to any one of claims 10 to 14 further including a second engaging region for engaging a tool which rotates the second screw portion relative to the second member.

16. A fixation device according to any one of claims 10 to 15 further including retaining means for retaining the fixation device within the threaded bore.

17. A fixation device according to any one of claims 10 to 16 further including a canal facilitating passage of the fixation device over a guide wire.

18. A tool for positioning a fixation device inside a threaded bore in a first and second member, the tool including:

(a) a first engaging portion for engaging part of the fixation device which rotates relative to the first member;

(b) a second engaging portion for engaging part of the fixation device which rotates relative to the second member and operable independently of the first engaging portion; and

(c) a locking mechanism to lock movement of the first engaging portion relative to the second engaging portion.

19. A tool according to claim 18 further including a shaft with independently operable inner and outer shaft portions, wherein:

(a) the outer shaft portion is the first engaging portion; and

(b) the inner shaft portion is the second engaging portion.

20. A tool according to claim 17 or claim 18 wherein at least the first and second engaging portions are cannulated.

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David B Fitzpatrick

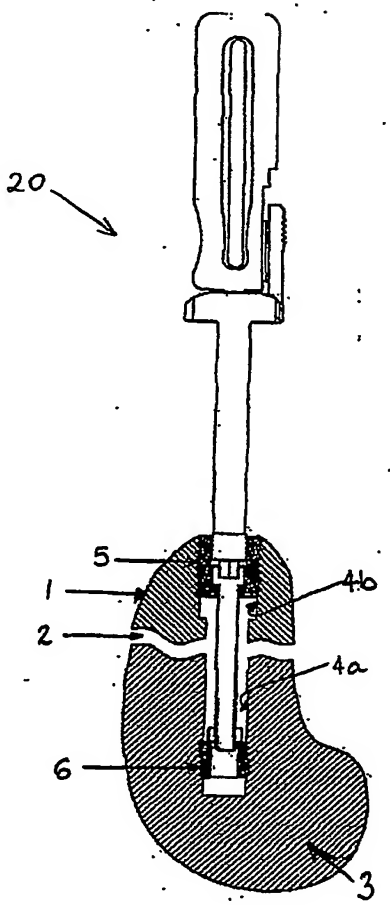

Figure 1a

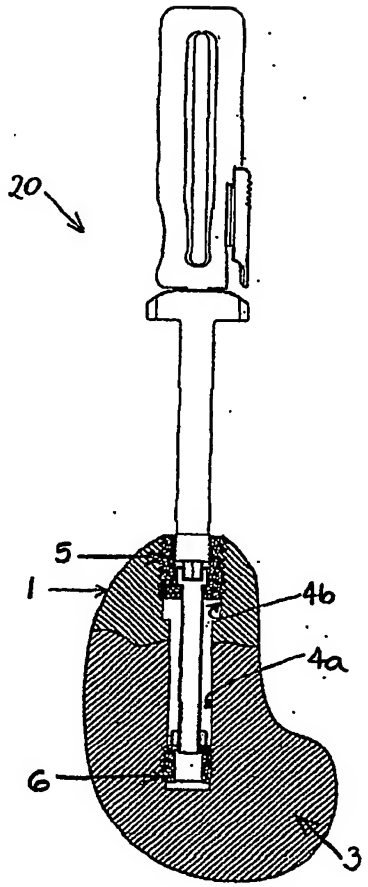

Figure 1b

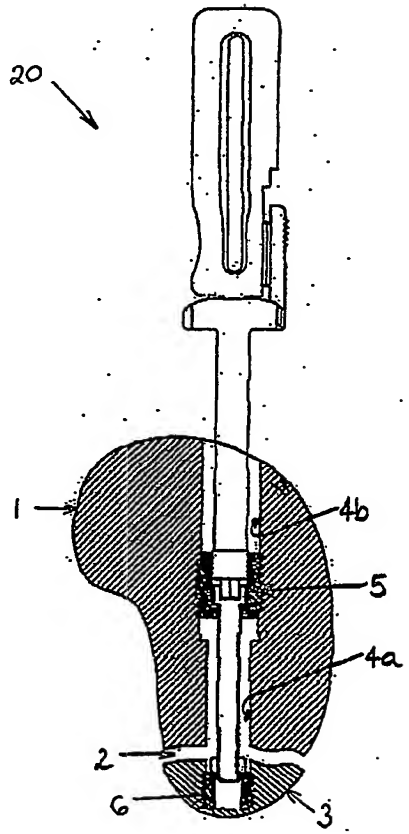

Figure 2a

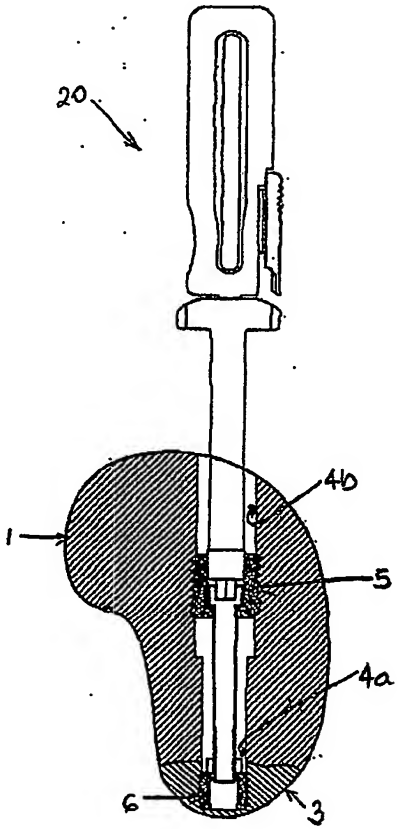

Figure 2b

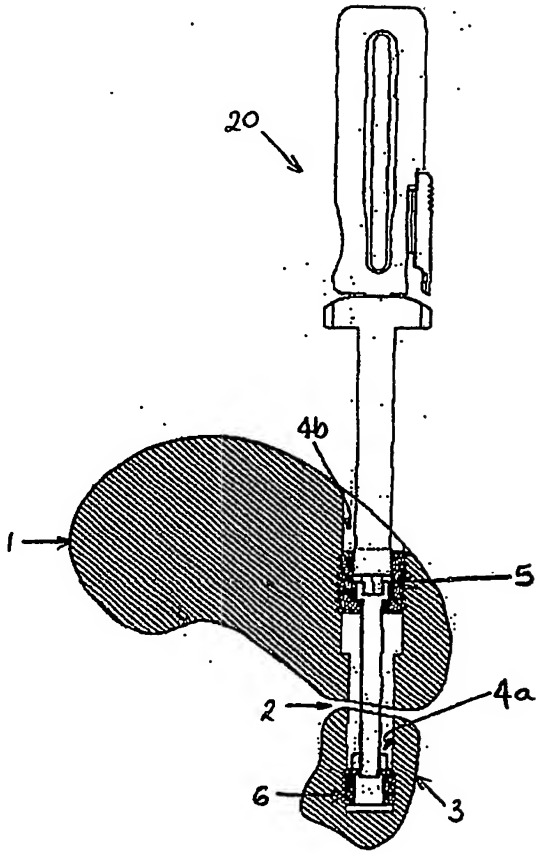

Figure 2c

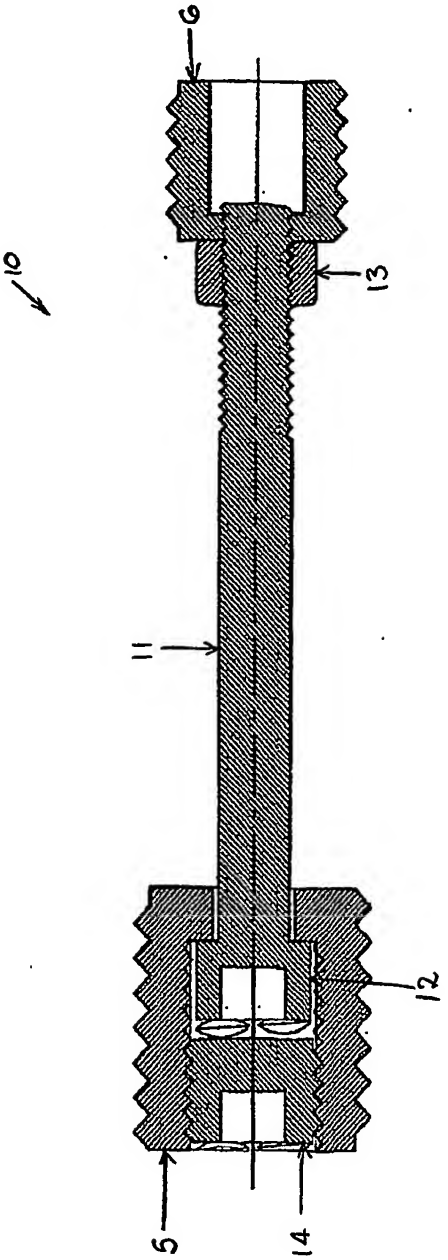

Figure 3

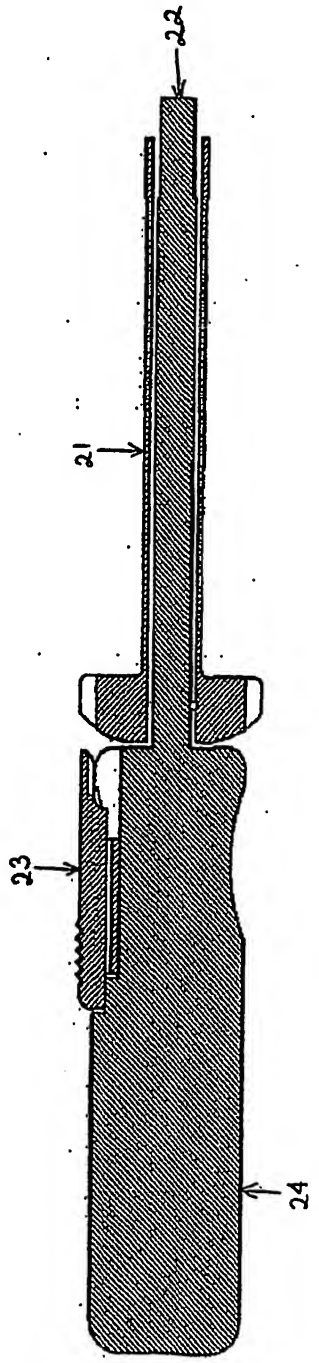

Figure 4a

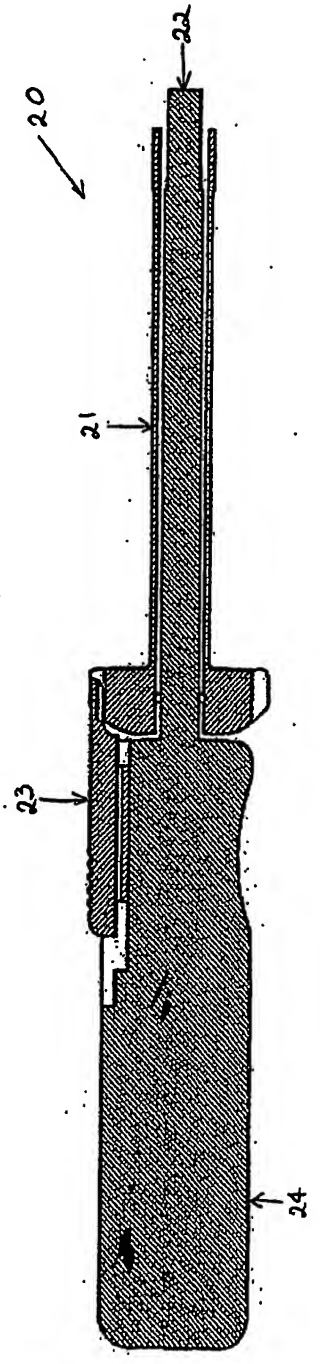

Figure 4b

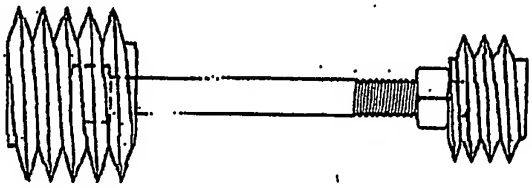

Figure 5a

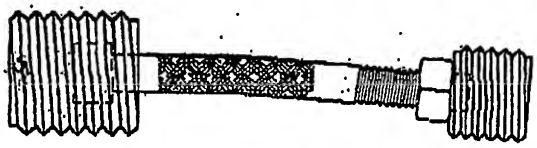

Figure 5b